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By: Debra K. Bauer

Date: May 5, 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Michael Graupe et al.

Atty Docket No.: 1016US

Application No.: 10/035,783

Group Art Unit: 1626

Filed: 12/24/2001

Examiner: Shiao, Rei-Tsang

For NOVEL COMPOUNDS AND COMPOSITIONS AS CATHEPSIN S INHIBITORS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESTRICTION REQUIREMENT

The Examiner has made the following Restriction Requirement:

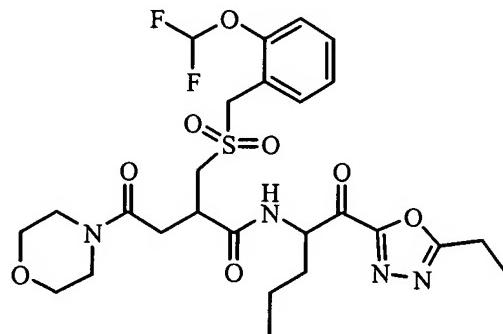
- I. Claims 8-9, 13-15 and 1-7, in part, drawn to compounds, Claim 28, in part, drawn to compositions, Claims 29-30, in part, drawn to methods of treatment, and Claim 31, in part, drawn to methods of making; Class 558, subclass various, wherein X¹, R³ and R⁴ are non-heterocyclic.
- II. Claims 10-12, 16-18, 19-21, 22-24 and 1-7, in part, drawn to compounds, Claim 28, in part, drawn to compositions, Claims 29-30, in part, drawn to methods of treatment, and Claim 31, in part, drawn to methods of making; Class 544-558, subclass various, wherein X¹, R³ and R⁴ are heterocyclic.
- III. Claims 25-27 and 1-7, in part, drawn to compounds, Claim 28, in part, drawn to

compositions, Claims 29-30, in part, drawn to methods of treatment, and Claim 31, in part, drawn to methods of making; Class 544-558, subclass various, wherein X¹, R³ and R⁴ are heterocyclic.

IV. Claims 1-7, in part, drawn to compounds, Claim 28, in part, drawn to compositions, Claims 29-30, in part, drawn to methods of treatment, and Claim 31, in part, drawn to methods of making; Class 544-558, subclass various, wherein X¹, R³ and R⁴ comprise compounds not encompassed by Groups I, II or III.

The Applicants further were required to elect a single disclosed species for examination.

The Applicants elect Group II and the species disclosed on page 546, line 9 and 10, of the specification having the following structure:



namely 2-(2-difluoromethoxy-benzylsulfonylmethyl)-N-[1-(5-ethyl[1,3,4]oxadiazole-2-carbonyl)butyl]4-morpholin-4-yl-4-oxo butyramide. The Applicants traverse the Restriction Requirement for the following reasons.

The Applicants submit that decisions by the Patent and Trademark Office Board of Appeals and its reviewing court clearly established that a restriction requirement which results in having the subject matter of a single claim divided into separate groups is improper. The Board and its reviewing court ruled that the Office may not refuse to examine a claim on the basis that it embraces independent

and distinct inventions. The Applicants cite *Ex parte Holt*, 214 USPQ 381 (Bd. Ap. 1982), *In re Haas I*, 179 USPQ 623 (CCPA 1973); *In re Haas II*, 198 USPQ 334 (CCPA 1978); and *In re Weber*, 198 USPQ 331 (CCPA 1978). The Court in *In re Weber*, summarized this principle as follows:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

In *In re Haas I* the examiner withdrew two generic compound claims from further consideration on the ground that they included multiple patentably distinct inventions. At the end of the prosecution a species claim was allowed along with a narrower generic claim encompassing only those compounds similar to the allowed species. The applicant filed a petition under Rule 144 (petition denied), requested reconsideration (reconsideration denied), and subsequently took the issue to the Board of Appeals, which held there was no statutory grounds for their appellate jurisdiction.

On appeal from the Board's decision, the Court of Custom and Patent Appeals held that an adverse action of this nature is a rejection and denial of substantive rights, review of which must fall within the jurisdiction of the Board. The Court remanded the case to the Board, which remanded the case to the examiner and the examiner then finally rejected the claims for misjoinder of invention under 35 U.S.C § 121. On appeal the Board affirmed the examiner's rejection. On appeal from the decision of the Board affirming the final rejection under § 121, the Court of Customs and Patent Appeals (*In re Haas II*) reversed on authority of *In re Weber* and held that “§ 121 does not provide a

basis for the rejection of a claim".

In *Ex parte Holt*, the Board of Appeals followed *In re Weber* and *In re Haas II* and granted relief to the Appellant on the basis that refusing to examine a claim because it embraced independent and distinct inventions was improper. The Board declared, "It is clear from Haas I that regardless of the language employed by the examiner, the refusal to examine a claim is, in effect, a rejection of that claim" (emphasis added).

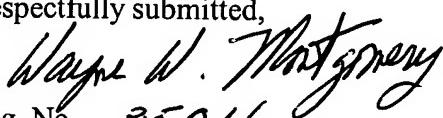
In light of *In re Weber* and *In re Haas*, the Patent and Trademark Office revised restriction practice with respect to generically claimed inventions. The proper procedure for restricting a generic claim is delineated in § 803.02 of the MPEP. The examiner may require an applicant to provisionally elect a subgenus for examination and if the elected subgenus is found unpatentable, the generic claim and claims to the elected subgenus are rejected and claims to the non-elected subgenera are withdrawn from further consideration. The applicant may overcome this rejection by amending the generic claim to exclude the unpatentable subgenus. If after reconsideration of the amended claim a second subgenus is found unpatentable, the claim is rejected and the action is made final. Thus, the prior art search is not extended unnecessarily and the applicant's invention, as he or she contemplates it, is examined on the merits.

In the present application, the Examiner has imposed a restriction requirement that divides the claimed invention into four subgenera. The Restriction Requirement would compel the Applicants to amend their generic claims to excise the non-elected subject matter. The Applicants will be forced to present claims to the excised subject matter in one or more separate applications. The Applicants assert that the prevailing law prohibits the use of 35 U.S.C. § 121 in this manner. The Applicants have a right to have their invention as they have claimed it examined on the merits. Accordingly, the Applicants request that the restriction requirement be withdrawn.

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Respectfully submitted,


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